Exhibit 2 – SEALED excerpts of Plaintiffs' Expert Witness Report of G. Caleb Alexander, MD, MS

Plaintiffs' Opposition to Defendants' Motion for Summary Judgment on Plaintiff Cabell County Commission's Right to Abatement

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Abatement Plan for Addressing the Opioid Crisis in Cabell County and the City of Huntington

Expert Witness Report of G. Caleb Alexander, MD, MS

August 3, 2020

Appendix A – Johns Hopkins Report: “From Evidence to Impact”

Appendix B – Curriculum vitae

Appendix C – List of sources that were consulted

Appendix D – Redress Model

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I. BACKGROUND AND QUALIFICATIONS OF AUTHOR

1. My name is G. Caleb Alexander. I am a practicing general internist and Professor of Epidemiology and Medicine at Johns Hopkins Bloomberg School of Public Health. I have been retained by Plaintiffs to provide my scientific expertise regarding the opioid epidemic, nationally and in the Cabell-Huntington Community (the "*Community*"), an Appalachian community rich in heritage that has been devastated by the opioid epidemic.[a] I have been asked to discuss ways to abate or reduce the harms caused by the oversupply of opioids into the Community. I have also been asked to estimate the size of specific populations that may require abatement interventions within the Community over a 15-year period, from 2021 to 2035, and to provide recommended cost estimates for certain abatement interventions (generally medical costs); the remaining costs are provided in the expert report of local forensic economist George A. Barrett. In his report, Mr. Barrett also calculates the total cost of my recommended abatement plan.

2. As a physician, I am responsible for the primary care of approximately 250 patients, most of whom live in and around Baltimore County. I have clinic one half-day per week and I am also responsible for patient care matters that arise at other times. The patients that I see range from young adults to nonagenarians (aged 90 – 99 years), and as a primary care physician I oversee their acute, preventive, and chronic needs, which include conditions such as asthma, diabetes, hypertension, osteoporosis, chronic pain, anxiety, and depression. While I do not specialize in the care of patients with opioid use disorder (OUD),[b] I have patients in my practice with OUD who I co-manage with addiction specialists, and I care for patients who have lost family members to fatal opioid overdoses.

3. In contrast to my work as a physician, as a pharmacoepidemiologist, I focus on "the study of the uses and effects of drugs in well-defined populations."[1] Pharmacoepidemiology is a bridge discipline that combines insights and tools from clinical medicine, pharmacology, and epidemiology to generate fundamental new knowledge regarding the utilization, safety, and effectiveness of prescription drugs. It also concerns itself with understanding the effects of pharmaceutical policy, such as regulatory or payment policies that influence prescription drug use. As a pharmacoepidemiologist, much of my work has focused on the nature, quality, and determinants of prescription drug utilization in the United States, although I have also conducted or participated in many investigations examining the safety of specific products. I have used many different data for this work, often data that has already been assembled for other purposes, such as administrative claims data from health plans or large national surveys.

[a] Plaintiffs are Cabell County Commission and the City of Huntington, West Virginia. Throughout this report, the Cabell-Huntington Community or the Community refers to the entire community of Cabell County and the City of Huntington.

[b] Definitions of terms such as "opioid use disorder", "addiction", "non-medical opioid use", and "misuse" are provided in Dr. Katherine Keyes' expert report.

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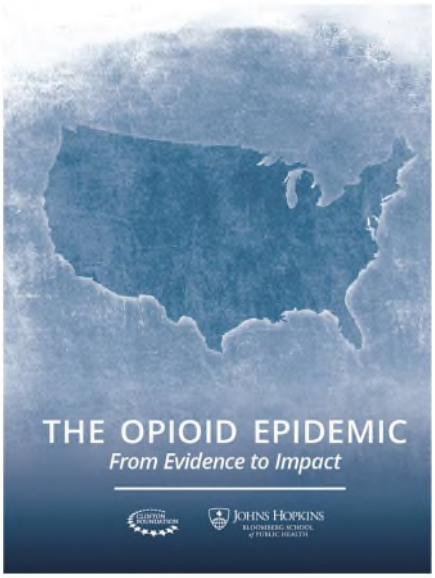
4. During the past decade, I have devoted much of my professional time to addressing the opioid epidemic. I have served as one of three Co-Editors of monographs issued by the Johns Hopkins Bloomberg School of Public Health providing comprehensive, concrete, evidence-based solutions to the epidemic. These monographs were issued in October 2015 and October 2017 (**Figure 1**); the latter report is provided as **Appendix A**. I have also testified in front of the U.S. Senate and the U.S. House of Representatives; briefed groups such as the National Governors Association, the Food and Drug Administration, Congressional Black Caucus, Centers for Medicare and Medicaid Services, and the National Academy of Science, Engineering and Medicine; and participated in efforts to improve the safe use of prescription opioids within Johns Hopkins Medicine and other health systems. My work focused on the epidemic has been funded by the Department of Health and Human Services Assistant Secretary for Planning and Evaluation (DHHS/ASPE), the Centers for Disease Control and Prevention (CDC), the Robert Wood Johnson Foundation, and the National Institutes of Health (NIH).

Figure 1. Report on the Opioid Epidemic



5. I have published extensively about opioids, including analyses of prescription opioid use in the U.S.[2,3] as well as evaluations of the structure and impact of regulatory[4,5,6,7,8,9,10,11,12,13,14,15,16,17] and payment[18,19,20,21,22] policies on opioid prescribing, dispensing, and utilization. I have also co-authored policy perspectives,[23,24] a widely referenced public health review of the epidemic,[25] and a recent analysis of the potential impact of the coronavirus pandemic on the care of individuals with OUD.[26]

6. In addition to these studies, I have also led or participated in teams examining many other facets of the crisis, including: availability of naloxone in retail pharmacies;[27] opioid initiation among members of households with a prescription opioid user;[28] the effect of reformulated Oxycontin on opioid utilization;[29] physicians' knowledge and attitudes regarding non-medical opioid use;[30] use and impact of medication for opioid use disorder (MOUD);[31,32,33] the costs and healthcare utilization associated with high-risk opioid use;[34] use of automated algorithms to identify non-medical opioid use;[35] the relationship between high-risk patients receiving prescription opioids and high-volume prescribers;[36] opioid use and safety among individuals with human immunodeficiency virus (HIV),[37,38] chronic kidney disease,[39,40,41] or recent surgery;[42,43,44,45,46] and potential financial conflicts of interest among organizations opposed to the CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain.[47,48]

7. The studies I have performed examining the opioid epidemic have used a variety of epidemiologic methods, including: descriptive analyses based on cross-sectional, serial cross-sectional, and period prevalence designs; retrospective cohort studies using difference-in-difference, interrupted time-series, comparative interrupted time-series, and time-to-event designs; prospective cohort studies; qualitative assessments using grounded theory; and narrative and systematic reviews. A complete list of my publications is contained in my curriculum vitae (**Appendix B**).

8. In the first bellwether trial case in *In re: National Prescription Opiate Litigation* before Judge Dan Polster, I served as an expert witness on the nature of the opioid epidemic, both nationally and in the bellwether counties, and on evidence-based and evidence-informed approaches to abate the epidemic.

I provided an expert report and was deposed in that case. I have also served as an expert witness in *State of Washington v. Purdue Pharma*, where I offered an opinion on the nature of the epidemic in Washington, and crafted an evidence-based and evidence-informed abatement plan to effectively address the epidemic there.

9. I received a B.A. cum laude from the University of Pennsylvania (Philosophy) in 1993, an M.D. from Case Western Reserve University in 1998, and an M.S. from the University of Chicago in 2003. A more complete description of my qualifications is found in my curriculum vitae. I performed this work through Monument Analytics, a health care consultancy that I cofounded that is separate and distinct from Johns Hopkins, and I was assisted during this process by Monument Analytics' employees and consultants. My rate of compensation for this matter is $900 per hour. I am also reimbursed for my out-of-pocket expenses. I am not compensated based on the outcome of this matter nor the substance of my report.

10. The opinions and conclusions in this report are based on the information and documentation that was available to me at this time, and they are my own, rather than those of Johns Hopkins University. I reserve the right to supplement and revise these perspectives based on additional evidence or information that is made available to me after the date of this report.

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II. DATA SOURCES, METHODOLOGY AND OPINIONS

11. In preparing this report, I reviewed materials from a number of sources, including: Bates-stamped documents and deposition testimony in this case provided to me by counsel; published reports regarding the epidemic; information derived from other local and national; and peer-reviewed literature, whitepapers, reports from public health authorities, non-profit organizations, and other publicly available sources. I, along with some of my team members, have also spoken with many local stakeholders:

- David Chaffin, MD, FACOG, Professor, Marshall University
- Ray Cornwell, Police Captain, Huntington Police Department
- Todd Davies, PhD, Assistant Professor, Marshall University; Cabell-Huntington Coalition for the Homeless, Executive Director
- Hank Dial, Police Chief, Huntington Police Department
- Zach Hansen, MD, Doctor, Valley Health
- Tim Hardesty, Assistant Superintendent, Division of District Support and Employee Relations, Cabell County Schools
- Rocky Johnson, Police Captain, Special Investigations Bureau (Former), Huntington Police Department
- Michael Kilkenny, MD, Director, Cabell County Department of Public Health
- Marcia Knight, Director of Education, Cabell County EMS
- Sean Loudin, MD, Associate Professor, Marshall University School of Medicine
- Gordon Merry, Director, Cabell County EMS
- Steve Murray, Assistant Director, Cabell County EMS
- Lyn O'Connell, PhD, Associate Director of Addiction Sciences, Marshall Health
- Stephen Petrany, MD, Chair of Family & Community Health, Marshall University School of Medicine
- Jan Rader, Fire Chief, Huntington Fire Department
- Keith Thomas, Coordinator of Student Support, Cabell County Schools
- Ellen A. Thompson, MD, Professor, Marshall Health
- Kelly Watts, Assistant Superintendent, Division of Instruction and Leadership, Cabell County Schools
- Beth Welsh, Associate Director of Operations for Addiction Sciences in Family Medicine, Marshall University
- Steve Williams, Mayor, City of Huntington
- Chuck Zerkle, Sheriff, Cabell County Sheriff's Office

Many of my findings are based on prior investigations that my team and I have either performed or synthesized, such as knowledge contained in **Appendix A** and in citations such as references #1-#48. A complete list of the documents I consulted in preparing this report is provided as **Appendix C**.

12. Several prior reports, such as the West Virginia 2020-2022 Substance Use Response Plan,[49] City of Solutions Guide,[50] 2015 and 2017 Mayor's Strategic Plans,[51,52] and key components of the Cabell County Resiliency Plan[53] are relevant to my report given their authorship and focus. The Cabell County Resiliency Plan is especially germane given its comprehensiveness, recency and local applicability. It sets forth evidence-based interventions that are consistent with those proposed herein as well as those that have been proposed in other local plans and plans nationwide. My goal was not to recreate or replace the Cabell County Resiliency Plan or other proposals, but rather, to complement them with

additional analysis that includes: (a) a more detailed examination of the scientific evidence-base underlying varied abatement interventions; (b) estimates of the size of specific populations in need, such as the number of individuals within the Community that have HIV attributable to opioid use; (c) additional interventions that complement local plans, such as academic detailing, a specialized overdose law enforcement unit and community-wide naloxone "lock boxes". The population estimates presented in my Redress Model, enclosed as **Appendix D**, are derived from data from local government entities (e.g., Cabell Huntington Health Department, Cabell County Emergency Medical Services), federal agencies (e.g., Centers for Disease Control and Prevention [CDC], Substance Abuse and Mental Health Services Administration [SAMHSA], Department of Justice), community-based organizations (e.g., Harm Reduction Coalition), peer-reviewed publications, and both my and others' expert opinions. The selection of each estimate was driven by the strength of evidence and appropriateness of the data for the specific context at hand. I discuss my approach to evaluating evidence further in Paragraphs #14 and #15. Overall, I took a conservative approach to derive the population estimates included in my Redress Model.

13. The layout of my Redress Model mirrors the layout of this report. For each abatement intervention, I list the estimated size of the target population, how it was derived and the sources that I used. For example, I used data from the U.S. Fire Administration, Cabell County Emergency Medical Services, and local police and Sheriff's departments to estimate the number of first responders (firefighters, emergency medical technicians [EMTs] and paramedics, and police officers) in the Community that should be provided with naloxone and training regarding its use. For each abatement category, I first estimate the size of each relevant population for 2021 and then I project how these populations are likely to change over a fifteen-year period from 2021 through 2035. For example, I project changes in the number of first responders using annual employment growth rates based on data from the U.S. Department of Labor, Employment & Training Administration (West Virginia O-NET data). More information regarding the sizes of different populations, as well as the methods that I used to project them over time, is provided within the Redress Model.

14. My review of the scientific evidence base was based on a stepwise process building on the foundation of literature regarding the opioid epidemic that I was already aware of. To supplement my knowledge, I reviewed the content of additional academic and governmental studies, including both their reference lists as well as subsequent reports that have cited them. I also reviewed reports such as those discussed in Paragraph #12 for additional sources of scientific information. Finally, in some instances, additional candidate articles were identified based on keyword searches of major bibliographic databases such as PubMed. In evaluating studies, I used a number of qualitative criteria that are often useful in evaluating the strength of scientific evidence supporting a given scientific finding or claim. These include factors such as the publishing journal, authorship team, affiliated institutions, funding source(s), data source(s), methodologic approach, and interpretation.[c] The "Hill Criteria" (strength of association, consistency, specificity, temporality, biological gradient, plausibility, coherence, experiment, and analogy) are also an important means of evaluating the strength of causal inference possible from a given scientific study, and I have applied this criteria as well.[54]

15. For some remedies to abate the Community's opioid epidemic, such as OUD treatment or naloxone distribution and training, the evidence-base is vast, with thousands of peer-reviewed manuscripts examining this matter. In these settings, formal evidence syntheses were often available, typically

[c] Neither these criteria nor the Hill Criteria are absolute. Rather, they serve as contextual factors that provide qualitative information that can be useful in examining the credibility of scientific claims.

systematic reviews that represent a pre-specified, transparent, reproducible, highly structured approach to curating and critically appraising the totality of information required to address a carefully specified question. Because of their comprehensiveness and rigor, such evidence-syntheses are often regarded as at the top of the "evidence pyramid".[55] For some abatement interventions, I also used information available from authoritative sources such as the CDC, National Institute on Drug Abuse (NIDA), or SAMHSA.

16. There is widespread consensus in both clinical and public health communities that the abatement measures identified in this report are effective in reversing opioid-related morbidity and mortality. The measures discussed herein are consistent with the Resiliency Plan, the Mayor's Office plans, and the State's Opioid and Substance Response Plans, and have been put forth by numerous consensus panels, task forces, professional society organizations and others. Disagreement about these solutions, when present, has tended to focus more on the priority of the interventions given limited funding (e.g., how much should be spent on law enforcement vs. MOUD,[56] as well as in some cases, the potential unintended effects of some interventions. Fortunately, there is a large evidence base to guide the selection of interventions that should be undertaken in the Community, and also a recognition of the critical point, as expressed by former Congressman John Delaney, "that the cost of doing nothing is not nothing".[57]

17. I conclude that an opioid epidemic currently exists within the Community. This epidemic continues to result in high levels of opioid-related morbidity and mortality as described in this report and in materials that I have reviewed to prepare it. I further conclude, based on my experience in epidemiology, clinical medicine, and public health, my extensive application of these fields to the opioid epidemic and my analysis in this case, including review of the Resiliency Plan and other Community materials, that I am able to determine what additional evidence-based and evidence-informed measures and approaches should be used to reduce opioid-related harms. These measures and approaches are described below. The specific utilization and combination of measures should be subject to the opinions of stakeholders, policy-makers, and subject matter experts in the Community.

18. Based on the sweeping scientific support for the abatement interventions I have proposed herein, many of which have already been implemented in the Cabell-Huntington Community, I believe that coordinated, all-encompassing efforts that respond to the evolving epidemic could reduce cumulative opioid overdoses and opioid-related harms by 50% over fifteen years.[58] These findings, in addition to the research I have conducted throughout my career, have informed the timeline for my Redress Model. In addition, as I discuss later, interventions such as MOUD, naloxone distribution, and harm reduction programs don't just make good public health sense, they also make good economic sense with positive returns on investment (Paragraph #227).

19. The next sections of my report discuss indicia of the opioid epidemic in the United States as well as the Community. After that, I discuss principles that should govern an effective response, misconceptions that must be addressed, and the importance of customizing abatement efforts to the needs of the Community's unique Appalachian cultural and heritage.

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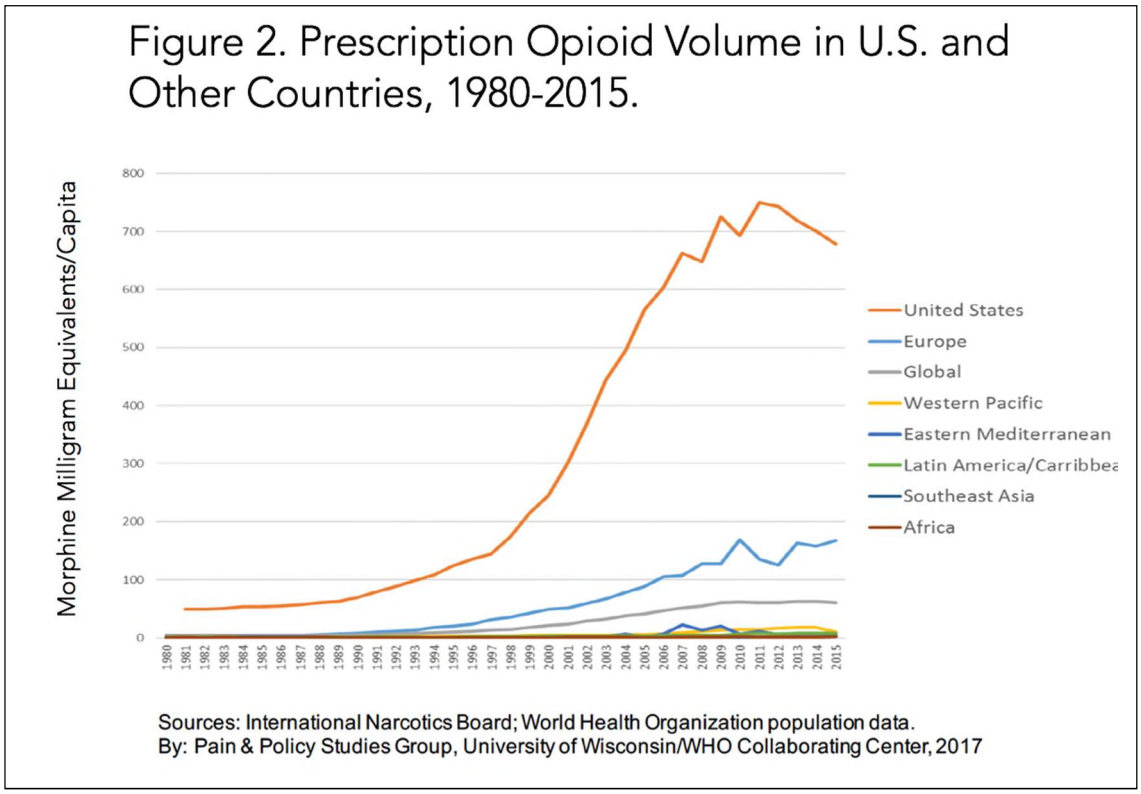
III. INDICIA OF OPIOID CRISIS AND ABATEMENT EFFORTS IN THE CABELL-HUNTINGTON COMMUNITY

20. Between 1992 and 2010, the volume of opioids prescribed in the U.S. increased by approximately 400 percent.[59] Rates of addiction, overdose deaths, and many other opioid-related harms increased in parallel.[60] Between 1999 and 2018, nearly 450,000 individuals in the U.S. died from a opioid overdose.[61] In 2017 alone, an estimated 47,600 people died in the U.S. from opioids, more than from motor vehicle accidents, suicide, gun violence, or AIDS at the peak of that epidemic.[62] For each year between 2015 and 2017, life expectancy in the U.S. declined, fueled in part by the opioids epidemic.[63] The origins of the present-day national opioid epidemic are described further in the expert report of Dr. Daniel Ciccarone. Despite modest declines in opioid use since 2010, they remain vastly overused, both relative to pre-epidemic baseline as well as to other parts of the world (**Figure 2**). This overuse is a key driver of ongoing injuries and deaths from the epidemic.



21. The devastation from the opioid epidemic, which has been closely linked to prescription opioid oversupply, is especially severe in the Cabell-Huntington Community, which has been referred to as the "overdose capital of the world".[64,65] At the peak of opioid prescribing, in 2012, the opioid prescribing rate in Cabell County was twice the overall rate in the U.S. (167.5 vs 81.3 per 100 residents, respectively).[66,67] In 2015, 40 *million* opioid prescriptions entered Cabell County, enough for more than 400 pills for every adult and child in the County.[68] Despite significant reduction in the opioid prescribing rate, the 2018 opioid prescribing rate in Cabell County remains nearly two-times higher than the overall rate in the U.S. (92.1 vs 51.4 per 100 residents, respectively).[69]

22. This oversupply of opioids has contributed to a "synergistic epidemic", or syndemic – the worst type of opioid epidemic – due to the high rates of mortality across multiple opioid classes and linked health problems that result in excess burden in the population.[70] Between 2001 and 2016, the number of

individuals in West Virginia that have died from an overdose increased four-fold.[71] At least 83% of these overdoses were caused by an opioid overdose.[72] Though the sharp rise in opioid deaths in West Virginia has largely been driven by heroin and fentanyl since 2014, between 2014 and 2016, deaths due to prescription opioids increased by 42%.[73] Within a six-hour time window on August 15, 2016, twenty-six people overdosed on opioids in Huntington.[74] In 2017, emergency services in Cabell County responded to, on average, over five overdoses a day;[75] 152 of these overdoses were fatal.[76] In 2019, there were 754 overdose-related visits to the two emergency departments (ED) in Cabell County.[77] For every life that has been lost, countless others have been affected by OUD or other collateral harms, further decimating this close-knit Appalachian community.

23. During the past decade, the opioid epidemic in the Community has been further complicated by an abrupt rise in heroin-related overdoses and overdoses from synthetic opioids such as illicitly manufactured fentanyl.[d] There is a clear link between non-medical use of prescription opioids and subsequent heroin or illicit fentanyl use – for example, heroin and fentanyl are close chemical analogues to prescription opioids.[78] In addition, several studies suggesting that 70-80% of current heroin users report non-medical prescription opioid use prior to initiating heroin.[79,80] An investigation conducted in Cabell County between June and July 2018 estimated that 1,857 residents inject drugs, amounting to one in forty (2.4%) adults in the Community.[81] Of those surveyed, more than three in five (63.5%) used prescription pain medications and 21.7% injected prescription pain medication; four in five (82%) injected heroin and over half (51.7%) injected fentanyl. Between 2012 and 2017, overdose deaths due to fentanyl increased over 20% in West Virginia.[82]

24. The incidence of neonatal abstinence syndrome (NAS) is also markedly elevated, with rates ten-times higher in Cabell County than the rest of the U.S.[83] Between 2007 and 2013, the incidence of NAS quadrupled in West Virginia, from 7.74 to 31.56 per 1,000 live births.[84] In 2017, there were 62.3 NAS cases per 1,000 births in Cabell County.[85] Nearly one-in-five (17.6%) of umbilical cords tested positive for opioids at Cabell Huntington Hospital.[86] West Virginia babies born with NAS during this time were 2.5-times more likely to have respiratory diagnoses, 3.7-times more likely to have feeding difficulties, and 7.5-times more likely to have seizures. From October 2016 to December 2017, it is estimated that around one in ten births (10.5%) in West Virginia were babies diagnosed with NAS. Within the substate region that contains Cabell County, around 670 infants were diagnosed with NAS.[87] The West Virginia Department of Health and Human Resources estimates that one in seven (14.3%) babies born in the state may experience long-term consequences resulting from drug exposure during pregnancy.[88]

25. In addition to the high number of infants born with NAS, the opioid epidemic has led to an increase of children being placed in foster care. Between 2009 and 2018, the number of children in foster care in West Virginia increased from 4,237 to 7,138.[89] In 2016, nearly one in five (16%) of the foster care placements in West Virginia were infants and half (47%) were due to parental substance use.[90] Youth in the Community are adversely affected by substance use in their families, peer groups and broader community. In 2016, 4% of middle and high school students in Cabell County reported the use of prescription drugs in the past 30 days.[91] Our own work suggests an increased risk of opioid initiation among household members of those prescribed opioids[92] – including an increased risk of opioid

[d] More recently still, the increasing presence of synthetic opioids in illicit drugs such as cocaine and methamphetamine, as well as rising stimulant-related deaths, has raised new concerns. Polysubstance use is common among individuals with OUD. While a comprehensive review of other use disorders (e.g., tobacco, alcohol, stimulants) is beyond the scope of this report, abatement approaches to reduce opioid-related harms must be informed by the presence of other use disorders among many with OUD.

overdose among adolescents and young adults.[93] Between January 2019 and March 2020, there were 122 overdose-related visits to Cabell County EDs for youth aged 19 years and younger.[94]

26. Harms from the opioid crisis have not gone unchecked, and despite a severe lack of resources, the Community has nevertheless mobilized in many ways to address the challenges head-on, including through increased prevention (e.g., take-back programs); harm reduction (e.g., syringe services, naloxone distribution and training); and treatment (e.g., MOUD). For example, one of the lessons from the August 2016 overdose crisis is the importance of reaching out to hospitalized individuals to link them with ambulatory OUD treatment.[95] Project Engage, which has been implemented in Cabell Huntington Hospital and St. Mary's Hospital, combines substance use disorder (SUD) screening in EDs and inpatient units with "warm handoffs" between clinicians and peer recovery specialists to link individuals to treatment. In 2018, the Provider Response Organization for Addiction Care Treatment (PROACT) opened to serve as a community-hub for SUD treatment and referral services.[96] PROACT bridges gaps in treatment by addressing the clinical, behavioral, and spiritual components of SUD. Additionally, PROACT expands medications for addiction treatment (MAT) capacity within Cabell by engaging multiple providers to serve in the clinic part-time, instead of employing one full-time physician.[97]

27. Similarly, concerns regarding the effect of OUD on pregnant women, new mothers and infants have led to remarkable transformation in the Community's systems of care to manage OUD among expectant mothers and their offspring. In addition to universal screening of pregnant women, babies with NAS are provided specialized care in the Neonatal Therapeutic Unit at Cabell Huntington Hospital and Lily's Place. MOUD is available to women through the Maternal Addiction Recovery Center (MARC) or Maternal Opioid Medical Support (MOMS),[98] while the Knowledge in Developmental Steps (KIDS) Clinic offers speech, language, feeding, and psychological or psychosocial services to children with NAS.[99] Though much is still unknown regarding the long-term trajectories of children with NAS, young children born with NAS have increased risk of socio-behavioral abnormalities[100] and poorer school performance[101] indicating that neurocognitive and physical effects may persist through adolescence and require expanded services into adulthood.[102]

28. Another important component of the Community's response to the epidemic has been the provision and expansion of harm reduction services. In 2015, the Cabell Huntington Health Department implemented the first Harm Reduction and Syringe Services Program (SSP) in West Virginia and has served as a model for Harm Reduction Programs throughout the region. The SSP has been effective at reaching and delivering services to residents. In 2016, the SSP served nearly 2,000 clients, distributed 300,049 syringes, and collected 232,067 syringes.[103] By September 2019, there were more syringes being turned into the program than given out.[104]

29. These and other responses reflect a high degree of collaboration between community organizations and other stakeholders,[e] and fortunately, there are glimmers of hope, with preliminary data suggesting a 22-26% decline in opioid-overdose deaths between 2017 and 2018 in Cabell County.[105] Additionally, the efforts of the Harm Reduction Program have coincided with reductions in the rate of new HIV infections linked to injection drug use, and without the program, the incidence of HIV diagnoses may have been over two-times higher than the current level.[106] However, for every glimmer of hope, there are other signs that the epidemic is as active as ever,[107] many barriers persist, programs are vastly under-

[e] Such stakeholders include the Cabell Huntington Health Department, Marshall University, Marshall Health, Cabell Huntington Hospital, Saint Mary's Medical Center, and the City of Huntington.

resourced and the Community remains hard pressed to address them while simultaneously addressing strong adverse environmental and social factors that continue to fuel the epidemic.[108,109] As but one example of the seriousness of the current challenges, Cabell County EMS reported that the number of overdoses they responded to in May 2020 were two to three times higher than the prior nine months.[110,111]

30. This is of particular concern because, as we[112] and others[113,114] have argued, the novel SARS-CoV-2 coronavirus (COVID-19) pandemic injects new urgency into efforts to address the opioid epidemic, given that it comes at a time when our country's response to the opioid epidemic was just starting to coalesce. One major concern is that the pandemic has disrupted care, including access to medications for addiction treatment, for many with OUD. Fortunately, SAMHSA,[115] the Drug Enforcement Administration,[116] and Centers for Medicare and Medicaid Services have responded by relaxing or clarifying rules and regulations so as to allow for greater provision of take-home methadone, remote prescription of controlled substances and reimbursement for telehealth services. Another is that many individuals with OUD have chronic comorbid conditions, as well as tobacco use, that place them at higher risk from critical illness or death should they become infected with COVID-19.[117] Yet a third major concern arises from the fact that addition is "a disease of isolation". For an already marginalized group, the social distancing and other measures instituted in response to the global pandemic pose particularly profound risks. As we argue in our recent analysis, referring to response efforts underway to meet the needs of those impacted by the opioid epidemic, "These efforts will require new partnerships, unprecedented use of technology, and the dismantling of antiquated regulations. The greatest strength of the treatment system has always been compassion and care for the most vulnerable—qualities needed now more than ever."[118]

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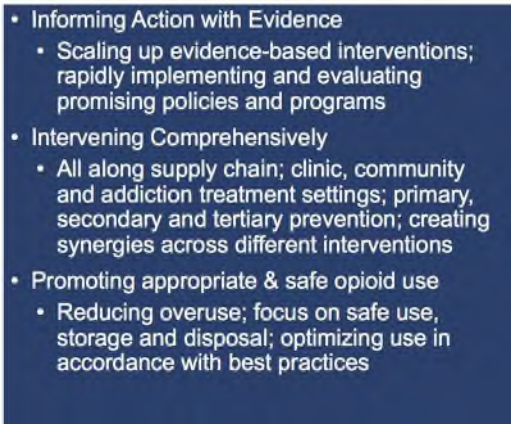
IV. PRINCIPLES GOVERNING EFFECTIVE RESPONSE

31. Despite the unprecedented injuries and deaths from the opioid epidemic, there is virtual consensus in the clinical, public health, and health policy communities that the epidemic can be abated. This consensus is reflected in the high concordance between a November 2017 report from the current Administration regarding the opioid epidemic,[119] a report that I Co-Edited and was released by the Johns Hopkins Bloomberg School of Public Health,[120] and other groups' recommendations to prevent further harms.[121,122,123] The Johns Hopkins report, enclosed as **Appendix A**, stemmed from three principles (**Figure 3**) that provide a valuable basis for current efforts.

Figure 3. Principles Governing Johns Hopkins Report: "The Opioid Epidemic: From Evidence to Impact".



32. In order to abate the epidemic, it is also important to eliminate common misconceptions about opioids and the ensuing epidemic, since inaccurate, misleading or false statements about the epidemic have allowed it to flourish. Examples of such misconceptions include:

Misconception #1: If a patient has "organic" pain, one need not worry about the addictive potential of opioids.
Reality: There is no evidence that organic pain prevents opioid addiction, and the notion that opioids are typically safe for chronic, non-cancer pain has contributed to their vast overuse.

Misconception #2: The primary driver of the epidemic is one of abuse, rather than addiction.
Reality: Abuse is a behavior and addiction is a disease; there are many lines of evidence demonstrating that addiction, rather than abuse, is the primary cause of opioid-related morbidity and mortality.

Misconception #3: The epidemic is largely driven by devious individuals such as rogue physicians and patients who are "doctor-shoppers".
Reality: Rogue physicians and "doctor-shoppers", while very important to identify and manage, account for a small proportion of opioid-related harms.

Misconception #4: If we constrain access to prescription opioids, it will just push people to heroin.
Reality: There are many factors that contribute to heroin use, and the potential for opioid policies "pushing" people to heroin underscores the need for significant treatment expansion in the United States.

V. ABATEMENT FRAMEWORK

33. There are three major categories of remedies that must be undertaken to address the opioid epidemic in the Cabell-Huntington Community.[f,g] First, we must improve the opioid prescription practices and the treatment of pain, since opioid oversupply has been a key driver of the epidemic.[124,125] Second, we must identify and treat individuals with OUD. This is important because even if prescription opioids were to be responsibly marketed, promoted, and used beginning tomorrow, there are still several thousand individuals in the Community with OUD, many of whom require active treatment and all of whom deserve access to care if and when treatment or recovery services are sought. Third, we must customize abatement remedies for specific subpopulations of the Community, including: pregnant women, new mothers, and infants; adolescents and young adults; families and children; the homeless and those with housing insecurity. We must also address the large number of individuals who may misuse opioids but who do not yet not fulfil formal criteria for OUD.

34. No *single* abatement remedy that is proposed can fully address the oversupply of opioids and associated morbidity and mortality in the Community; there are no magic bullets, and thus underscores the importance of intervening comprehensively as noted in the Cabell County Resiliency Plan. Also, some of the abatement remedies discussed may interact with one another in synergistic fashion, and successful implementation of some strategies may be dependent upon the simultaneous intervention of other strategies. For example, initiatives to decrease stigma and educate law enforcement and other community members about addiction may increase the demand for treatment, while expansions in treatment capacity to meet such demand may decrease rates of active OUD, which in turn may decrease overdose deaths and the need for naloxone. The dynamic nature of the epidemic, as well as the potential for these sorts of interactions, speaks to the vital need for surveillance and leadership as outlined in Section 1F. This will maximize the ability of communities to respond effectively to near real-time intelligence regarding key parameters of the epidemic and thus to use, and redirect, resources to maximize their public health value.

35. Some abatement approaches may be framed in the context of looking forward ten or fifteen years.[h] However, the legacy of the opioid epidemic will endure in the Cabell-Huntington Community far beyond that. This is because while OUD can be treated and may remit, it is not curable, and some individuals with OUD will require treatment indefinitely.[126,127,128] Others have acquired HIV and/or hepatitis C (HCV) as a result of an addiction that began with prescription opioids,[129,130] and they may require indefinite care for these comorbid conditions. Foster care for those orphaned by the epidemic, child welfare services, and services for children impacted by opioid use in utero must be resourced to address the needs of children and young adults as they grow and develop. Opioid use and its sequela also contribute to intergenerational trauma that propagates throughout time. For many, living healthy, productive lives in recovery is an active process, and thus to be successful, individuals must be supported with long-term resources to maximize their opportunities for success.

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[f] Other interventions are important in addressing the epidemic yet beyond the scope of this report, such as changes to coverage and reimbursement policies so as to improve options for pain treatment and reduce financial barriers to OUD treatment.

[g] While there are other ways to classify potential remedies, the elements within these remedies are remarkably consistent across different abatement proposals put forth locally and nationally, reflecting the widespread consensus about what needs to be done.

[h] This medium-term view strikes a balance – it is long enough to support infrastructure development and several cycles of planning and evaluation while avoiding some of the uncertainty entailed in trying to anticipate the magnitude of sequelae from the epidemic that may last decades or even generations.

36. Here and throughout, while I suggest remedies that should be included as part of a comprehensive abatement plan, and while I consider programs that are already underway, I leave it to the Community[i] to determine the degree to which further investment should be undertaken.

For each of the categories below, in the following sections of my report I provide background and scientific context, components of the proposed abatement interventions corresponding to each category, and concluding thoughts. Population estimates for each category are provided in the Redress Model (**Appendix D**).

- Category 1: Prevention – Reducing Opioid Oversupply and Improving Safe Use
  - 1A. Health Professional Education
  - 1B. Patient and Public Education
  - 1C. Safe Storage and Drug Disposal
  - 1D. Community Prevention and Resiliency
  - 1E. Harm Reduction
  - 1F. Surveillance, Evaluation, and Leadership

- Category 2: Treatment – Supporting Individuals Affected by the Epidemic
  - 2A. Connecting Individuals to Care
  - 2B. Treating Opioid Use Disorder
  - 2C. Managing Complications Attributable to the Epidemic
  - 2D. Workforce Expansion and Resiliency
  - 2E. Distributing Naloxone and Providing Training

- Category 3: Recovery – Enhancing Public Safety and Reintegration
  - 3A. Public Safety
  - 3B. Criminal Justice System
  - 3C. Vocational Training and Job Placement
  - 3D. Reengineering the Workplace
  - 3E. Mental Health Counseling and Grief Support

- Category 4: Addressing Needs of Special Populations
  - 4A. Pregnant Women, New Mothers, and Infants
  - 4B. Adolescents and Young Adults
  - 4C. Families and Children
  - 4D. Homeless and Housing Insecure Individuals
  - 4E. Individuals with Opioid Misuse

[i] Stakeholders include, but are not limited to, public health and law enforcement; treatment providers and systems; behavioral health providers and systems; educators; community advocates; employers; payers; and the courts.